IN THE CLAIMS

Please cancel claim 27 without prejudice to resubmission. Please amend claims 10, 20, 26, 28, 30-31 and 35 to read as follows.

B1

10. (Amended) A device for delivering a radioactive dose to a treatment zone, which device is suitable for insertion into a human or animal body, the device comprising:

G1

a stent; and

a flexible substrate comprising a therapeutic dose of a material selected from the group consisting of a radioactive material and a drug, and wherein said flexible substrate can be conformed to an area of the body in the treatment zone, and wherein said flexible substrate is located adjacent to said stent in the treatment zone.

G2

20. (Amended) The device of claim 13, wherein the foil sheet further comprises both said radioactive material and said drug.

G3

26. (Amended) A method for inserting a flexible substrate comprising a therapeutic amount of a material selected from the group consisting of a radioactive material and a drug, into a treatment zone in a human or animal body comprising the steps of:

associating the flexible substrate with an insertion device;

inserting the insertion device into a human or animal body;

positioning the flexible substrate at a desired position within the treatment zone; and

conforming the flexible substrate to an area of the body located within the treatment zone by radially expanding said insertion device; wherein the step of conforming the flexible substrate

A3 to an area of the treatment zone is accomplished by an insertion device selected from the group consisting of an expandable catheter and a stent.

A4 28. (Amended) The method according to claim 26, wherein the flexible substrate is located adjacent the outer diameter of the expandable catheter or stent.

A5 30. (Amended) The method according to claim 26, wherein the flexible substrate comprises a radioactive material and said radioactive material comprises palladium-103.

31. (Amended) The method according to claim 30, wherein the radioactive material comprises carrier-free palladium-103.

35. (Amended) The method according to claim 26, wherein said flexible substrate is a sleeve of an elastically deformable material which is expandable, and

A6 wherein said step of conforming said foil sheet to an area of the body comprises a step of expanding an internal support for said flexible substrate to conform said foil sheet to an area of the body and to maintain said flexible substrate in position in the treatment zone.

REMARKS

Responsive to the Office Action dated October 7, 2002, claim 27 has been canceled without prejudice to resubmission. Claims 1-26 and 28-35 are currently pending. Claims 10 and 26 have been amended for the reasons set forth below. Claim 20 has been amended to clarify the antecedents therein. Claim 28 has been amended to correct its dependence on a now-cancelled claim. Claims 30-31 have been amended to require the presence of the radioactive material as suggested by the Examiner. Claim 35 has been amended to improve its readability. A redline version of these claims is enclosed to show the amendments.

In the Office Action, claims 30-31 were objected to on the basis that they recite that the radioactive material is palladium-103 while independent claim 26, from which these claims depend, only says that the material can be a radioactive material or a drug. Although the applicant does not agree with this objection,[1] claims 30-31 have been amended to adopt the Examiner's suggestion for overcoming this objection. Favorable consideration and withdrawal of the objection are requested.

Claim 35 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Although the applicant does not agree with the rejection and considers that claim 35, prior to this amendment, was in compliance with 35 U.S.C. §112, second paragraph, some minor amendments have been made to claim 35 to improve its readability.

More specifically, claim 35 is a method claim dependent from claim 26. Claim 35 further defines two aspects of claim 26. First, claim 35 specifies that the flexible substrate of claim 26 is a sleeve of an elastically deformable material, which is expandable. Second, claim 35 then further defines the step of claim 26 that requires conforming the foil sheet to an area of the body by specifying that this step of conforming the foil sheet to an area of the body includes the step of expanding an internal support for the flexible substrate to cause the foil sheet to conform to an area of the body. It is considered that the wording of claim 35 is clear both prior to and after the amendment. If the Examiner disagrees, the Examiner is requested to provide an explanation of the rejection since no explanation was provided in the original objection, i.e. the Examiner did not explain why, in the Examiner's opinion, claim 35 was unclear.

Favorable consideration and withdrawal of the rejection of claim 35, as amended, under 35 U.S.C. §112, second paragraph, is requested.

In the Office Action, pending claims 1-35 have been rejected as being anticipated by U.S. Patent No. 6,261,320 to Tam et al. (hereinafter "Tam"). The applicant considers that the claims of the above-identified application are novel and inventive with respect to the Tam patent. Reconsideration is therefore requested for the following reasons.

The present invention, as claimed in claims 1-9, differs from the device set forth in Tam in that Applicant's invention requires two structural elements, namely, a stent and a foil sheet

[1] For example, claim 30 prior to the present amendment and, read as dependent from claim 26, would read, "A method for inserting a flexible substrate comprising a therapeutic amount of a material selected from the group consisting of palladium-103 and a drug, ..." This is a perfectly acceptable claim since it meets all of the requirements of 35 U.S.C. §112.

comprising a radioactive material and located adjacent to the stent. Tam describes a radioactive stent; thus, Tam's device lacks one of the two structural elements of applicant's claimed invention.

Applicant notes that the presently claimed structure provides many advantages over the radioactive stent of Tam. For example, radioactive sheets are more economically manufactured than radioactive stents. Also, the radioactive stents described by Tam must be produced in different sizes to fit the vessel requiring support; applicant's invention, however, can be conveniently trimmed to the necessary size at the time of use and can be used with non-radioactive stents that are already in inventory. These and other advantages of applicant's invention specifically result from the claimed two-element structure.

Claim 10 as amended herein also requires two separate structural elements, a stent and a flexible substrate, and therefore is also believed to be novel over the device described in Tam for the reasons set forth above.

Claim 26 as amended herein now includes the limitations of original claim 27, which is canceled in the present amendment. Thus, claim 26 now also requires two separate structural elements, the flexible substrate and an insertion device selected from a stent and an expandable catheter.

To further clarify the novelty of the present invention over the device set forth in Tam, applicant has amended Claim 26 to include the limitation that the flexible substrate is conformed to the treatment zone by radially expanding the insertion device. In the method exemplified in Tam, it is the radioactive stent itself that expands radially to conform to the vessel in which it is placed. Thus, claim 26 differs from Tam in that it requires both a stent and a flexible substrate and because the stent of claim 26 expands radially to conform the flexible substrate to the treatment zone, whereas in Tam there is no separate flexible substrate.

In addition, although Tam discloses that the stent can be inserted by a catheter insertion device, the catheter of Tam does not expand radially to conform a flexible substrate to the treatment zone as is now required by claim 26 of the present application. Thus, both the structure and the steps in amended claim 26 include elements that do not appear in Tam. Accordingly, claim 26 as amended is also believed to be novel over the method described in Tam.

Claims 2-9, 11-25, and 28-35 depend from independent claims 1, 10, and 26, respectively. Because the independent claims in the present application are believed to be novel over Tam, it follows that the dependent claims are also novel over Tam for at least the same reasons. Favorable consideration and withdrawal of the rejection of claims 1-26 and 28-35 under 35 U.S.C. §102(e) as anticipated by Tam, is requested.

In conclusion, all claims are considered to be novel in view of Tam for the reasons discussed above. In addition, all claims are considered to be inventive over Tam since Tam does not teach or suggest the features listed above which render the claims novel over Tam. Since the Office Action has not demonstrated that these features are taught in Tam, and has not shown that that there is motivation to modify the device or method of Tam to arrive at the present invention as claimed in the pending claims, all claims are considered to be inventive at least because the features listed above are not taught or suggested by Tam.

Respectfully submitted,

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Redline Version of Claims 10, 20, 26, 28 30-31 and 35 Showing Amendments

10. A device for delivering a radioactive dose to a treatment zone, which device is suitable for insertion into a human or animal body, the device comprising:

a stent; and

a flexible substrate comprising a therapeutic dose of a material selected from the group consisting of a radioactive material and a drug, and wherein said flexible substrate can be conformed to an area of the body in the treatment zone, and wherein said flexible substrate is located adjacent to said stent in the treatment zone.

20. The device of claim 13, wherein the foil sheet further comprises both said ~~a~~ radioactive material and said ~~a~~ drug.

26. A method for inserting a flexible substrate comprising a therapeutic amount of a material selected from the group consisting of a radioactive material and a drug, into a treatment zone in a human or animal body comprising the steps of:

associating the flexible substrate with an insertion device;

inserting the insertion device into a human or animal body;

positioning the flexible substrate at a desired position within the treatment zone; and

conforming the flexible substrate to an area of the body located within the treatment zone ~~using~~ by radially expanding said insertion device; wherein the step of conforming the flexible substrate to an area of the treatment zone is accomplished by an insertion device selected from the group consisting of an expandable catheter and a stent.

28. The method according to claim ~~27~~ 26, wherein the flexible substrate is located adjacent the outer diameter of the expandable catheter or stent.

30. (Amended) The method according to claim 26, wherein the flexible substrate comprises a radioactive material and said radioactive material ~~is~~comprises palladium-103.

31. (Amended) The method according to claim ~~26~~30, wherein the radioactive material comprises carrier-free palladium-103.

35. (Amended) The method according to claim 26, wherein ~~the~~ said flexible substrate is a sleeve of an elastically deformable material which is expandable, and

~~the~~ wherein said step of conforming ~~the~~ said foil sheet to an area of the body comprises ~~the~~ a step of expanding an internal support for ~~the~~ said flexible substrate to conform ~~the~~ said foil sheet to an area of the body and to maintain ~~the~~ said flexible substrate in position in the treatment zone.